DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

95142d

January 6, 2005

CBER-05-008

VIA FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Dr. Lewis Pollack
Senior Director, Regulatory Affairs
Nabi Biopharmaceuticals
12280 Wilkins Avenue
Rockville, MD 20852

Re: BLA STN #103945
Nabi-HB® [Hepatitis B Immune Globulin (Human)]

Dear Dr. Pollack,

The Office of Compliance and Biologics Quality (OCBQ) in the Food and Drug Administration's Center for Biologics Evaluation and Research has reviewed webpages on www.nabi.com for your product Nabi-HB® [Hepatitis B Immune Globulin (Human)] submitted under cover of Form FDA 2253 (copies enclosed). These webpages are misleading because they fail to reveal material facts regarding the risks associated with Nabi-HB and, therefore, misbrand Nabi-HB in violation of the Federal Food, Drug, and Cosmetic Act (the Act). See 21 U.S.C. 352(a), 352(n), and 321(n). By failing to include sufficient information on risks, you have encouraged the potentially unsafe use of Nabi HB.

Background

According to the FDA-approved professional labeling (PI), Nabi-HB is a sterile solution of immunoglobulin containing antibodies to hepatitis B surface antigen (anti-HBs). The PI states:

> Nabi-HB, Hepatitis B Immune Globulin (Human), is indicated for treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HbsAg positive persons and household exposure to persons with acute HBV infection . . .

The PI then further qualifies that statement with details about the applicable settings for each of those types of exposures for which Nabi-HB is indicated. The PI also includes detailed risk information including contraindications, warnings, precautions, and adverse reactions.

Failure to Reveal Material Facts

The following web pages (copies enclosed) present the indication for Nabi-HB but fail to provide risk information:

- Nabi Patients Webpage (http://www.nabi.com/patients/index.php) (Enclosure A)
- Nabi-HB Product Information Webpage (http://www.nabi.com/product.php?id=2) (Enclosure B)
- Nabi-HB Physicians Information Webpage (http://www.nabi.com/physicians/product.php?id=2) (Enclosure C)

The omitted risk information is necessary to qualify the effectiveness claims appearing on these webpages. We note that the Nabi-HB Product Information and Physicians Information webpages do contain links to the PI. Referring the reader to the PI located elsewhere, however, is not sufficient to provide the appropriate qualification or pertinent information about the risks associated with Nabi-HB. Cf. 21 CFR 202.1 (e)(3)(i).

Conclusion and Requested Actions

Your webpages misbrand Nabi-HB within the meaning of the Act because they fail to reveal material facts regarding the risks associated with the use of this product and are, therefore, misleading. See 21 U.S.C. 352(a), 352(n), 321(n).

We request that Nabi immediately discontinue or revise the webpages mentioned above. Please submit a written response to this letter within ten (10) business days of the date of this letter stating whether you intend to comply with this request, listing all violative promotional materials for Nabi-HB such as those described above, and explaining your plan for discontinuing use of such materials. Because the violations described above are serious, we request, further, that your submission include a plan of action to disseminate truthful, non-misleading, and complete information to the audiences that received the violative promotional materials. Please direct your response to me at the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, HFM-600, 1401 Rockville Pike, Rockville, Maryland 20852-1448. In all future correspondence regarding this matter, please refer to the BLA/STN number and to CBER-05-008. We remind you that only written communications are considered official responses.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Nabi-HB comply with each applicable requirement of the Act and FDA implementing regulations.

Failure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure A: Patients Webpage
Enclosure B: Product Information WebPage
Enclosure C: Physicians Information Wegpage